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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,829	04/09/2004	James M. Minor	10030215-1	1398

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/821,829	Applicant(s) MINOR, JAMES M.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11-20-2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Status

Claims 1-13 and 17-20 are pending and being examined

Claims 14-16 and 21-34 are canceled.

Response to Arguments

Objections to the Specification

Applicant's argument, see p. 11, first full paragraph, filed 20 November 2006, with respect to the occurrence of trademarks PCURVE and T-CHART have been fully considered and are persuasive. The objection to the specification has been withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

Applicant's arguments, see p. 11, Claims rejected under 35USC 112, second Paragraph, filed 20 November 2006, with respect to the indefinite claim language have been fully considered and are persuasive. The rejection of claims 1-13 and 17-20 has been withdrawn.

Claim Rejections - 35 USC § 112, First Paragraph

Applicant's argument, see p. 12, Claims rejected under 35USC 112, First Paragraph, filed 20 November 2006, with respect to the indefinite claim language have been fully considered and are persuasive. The rejection of claims 1-13 and 17-20 has been withdrawn.

Claim Rejections - 35 USC § 102

Claim 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et

al. ("Gene Expression Correlates Of Clinical Prostate Cancer Behavior", Cancer Cell, Vol.1, March 2002). The rejection is maintained for the reasons of record and in further view of the following.

Response to arguments

Applicant argues Singh et al do not disclose a plurality of samples taken from a heterogeneous tissue region and the formation of a plurality of characteristic signatures.

Regarding the argument that Singh et al does not teach a plurality of samples taken from a heterogeneous region, where the heterogeneous region is composed of two portions, where the first of the two portions is composed of two tissue types and the second of the two portions is devoid of the one of the two tissue types. Singh et al teach on p. 209, col. 1, 2nd full paragraph, "...samples of prostate tumors and adjacent prostate tissue not containing tumors (referred to as "normal") were collected from patients..."The heterogeneous tissue region being the prostate, the first portion having tumor and the second portion being devoid of tumor. This clearly and directly reads on the claimed limitation of the heterogeneous tissue region. It is also clear that plurality of samples were taken from a heterogeneous tissue region, in this case the plurality of samples is two samples. The breadth of the claim and teaching of the specification in the instant case do not place a requirement or provide a definition regarding the nature of a plurality.

Regarding the argument that Singh et al do not disclose the formation of a plurality of characteristic signatures. Singh et al teach the formation of a plurality of characteristic signatures for example in Figure 3 as a set of 12 genes. Based on the

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clarification provide in the interview and in the current claim set, the measured expression of each gene listed in figure 3 of Singh et al forms a characteristic signature and collectively the genes constitute a plurality of characteristic signatures. Further, as provided in table 1, the serum PSA level and Gleason score also are characteristic signatures and together form a plurality of characteristic signatures.

The rejection is maintained.

Claims 1-10, 12-13, and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Crosby et al. (US PG Pub 2003/0190689). The rejection is maintained for the reasons of record and in further view of the following.

Response to arguments

Applicant's arguments filed 20 November 2006 have been fully considered but they are not persuasive. Applicant argues Crosby et al do not disclose the formation of a plurality of characteristic signatures.

Crosby discloses multiple embodiments in which characteristic signatures are formed from values of a particular property consistent with the teaching of the disclosure of the instant application. Specifically, Crosby et al disclose in paragraph [0024] the identification of 4 novel biomarkers for predicting breast cancer responsiveness and 4 novel biomarkers for predicting glioma cancer and thereby forming a plurality of characteristic signatures. The term "biomarker" is considered to be an analogous term of art in relation to the term "characteristic signature" as used in the instant case. In paragraph [0025], Crosby et al. disclose the correlation of the biomarkers detected

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among all patients and the disease state. This point is further clarified in paragraph [0027], lines 1-4 and 8-19, stating that the exploitation of the biomarkers that are correlated to a therapeutic responsiveness among a group of patients have a certain disease will enable presently unavailable levels of predictive accuracy. This supports the assertion that Crosby et al form characteristic signatures. Similarly disclosed in paragraph [0028], another embodiment samples taken from a patient are analyzed for the biomarker and the results compared to a reference biomarker profile. The formation of characteristic signatures is further described in paragraphs [0092]-[0094] and examples 1-4.

The rejection is maintained.

Conclusion

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/
KRS

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

